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### (54) IMPROVED STENT CONFIGURATIONS

VERBESSERTE STENTKONFIGURATIONEN

AMELIORATIONS APORTEES A LA CONFIGURATION D'ENDOPROTHESES VASCULAIRES

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EP-A- 0 722 700	WO-A-87/04935
WO-A-96/03092	WO-A-96/25689
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DE-U- 29 703 879	US-A- 5 548 663

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EP 0 979 059 B1

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DescriptionBACKGROUND OF THE INVENTION1. Field of the Invention

[0001] This invention relates to stents of improved configuration which incorporate spiral articulations which unwind to form bracing structures or scaffolding upon expansion.

2. Brief Description of the Prior Art

[0002] Stents are radially expandable endoprosthesis which are typically intravascular implants capable of being implanted transluminally and enlarged radially after being introduced percutaneously. They have also been implanted in urinary tracts and bile ducts. They are used to reinforce body vessels and to prevent restenosis following angioplasty in the vascular system. They may be self-expanding or expanded by an internal radial force, such as when mounted on a balloon.

[0003] An example of a stent is shown in EP 0 421 729 which discloses a stent with segments connected together by coiled hinges.

[0004] WO 98/33546 is comprised in the state of art relevant to the question of novelty. This document discloses a stent with rotation joints.

[0005] In the past, stents have assumed many configurations and been made of many materials, including metals and plastic. Ordinary metals such as stainless steel have been used as have shape memory metals such as nitinol and the like. Stents have also been made of biodegradable plastic materials. They have been formed from wire, tube stock, etc.

SUMMARY OF THE INVENTION

[0006] This invention provides a new configuration for stents which may be adapted by all of the various types of prior art stents referred to hereinabove. There are numerous advantages to the new configuration. It limits recoil and adds resistance to compression for the expanded stent, among other things. It is longitudinally flexible in both the unexpanded and expanded conditions. It has several embodiments.

[0007] An important part of the new configuration includes a spiral or spiral-like structure comprised of joined elements which are coiled or bent and which unwind, uncoil or unbend to a more or less straightened condition on expansion of the stent. Such structures are hereinafter referred to collectively as coils, spirals or coil-like structures. These structures provide regions of low strain in the stent during expansion. These elements may be joined to each other or to any radially expansive members of any kind, annular serpentine members being preferred.

Brief Description of the Figures

## [0008]

8 Figure 1 is a flat view of one pattern embodiment of a stent configuration of the invention (unexpanded);  
Figure 2 is a detail of a portion of Figure 1;  
Figure 3 is an end view of a stent of the Figure 1 pattern according to the invention showing it in tubular configuration;  
Figure 4 is a showing of a stent in the embodiment of the preceding Figures in perspective and in an unexpanded configuration;  
Figure 5 is a showing of the stent of Figure 4 fully expanded with details of the front and rear of the stent;  
Figures 6, 7 and 8 are showings of the stent of Figure 4 in various stages of expansion with only details of the front of the stent shown for simplicity;  
Figure 9 is a plan view showing another embodiment of the invention;  
Figure 10 is a showing of a modified embodiment;  
Figure 11 is a showing of another embodiment;  
Figure 12 is a detail of a portion of FIG. 11;  
Figure 13 is a showing of the stent of FIGS. 11 and 12 in an expanded configuration;  
Figure 14 is a showing of another embodiment;  
Figure 15 is a showing of still another embodiment;  
Figure 16 is a showing of yet another embodiment;  
Figure 17 is a showing of still another embodiment; and  
Figures 18-28 show various spiral-like arrangements of the invention.

## 36 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0009] One preferred embodiment of the invention is illustrated in Figures 1-8. It comprises a metal tube-like structure 10 as best shown in Figures 3 and 4, such as nitinol or stainless steel, which has been etched or laser cut to the configuration shown in the plan view of Figures 1 and 2 and in a short version as shown in Figure 4. The configuration is made up of a series of serpentine annular expandable elements or segments 12 which form loops 14 to allow for radial annular expansion. Segments 12 may be other configurations but serpentine is preferred. Elements 12 are interconnected by pairs of elongated members 13a and 13b which are attached at one end to successive loops 14 of a segment 12 and which are joined at their other ends to adjacent pairs of elongated members 13a and 13b, as best seen in detail in Figure 2. Members 13a and 13b are preferably of narrower gauge than members 12 and are joined together in a coiled or spiral arrangement as shown generally at 16. Spiral 16 forms a structure about which members 13 may uncoil or unwind in a counterclockwise direction or clockwise direction to a substantially straight condi-

tion, depending on the spiral winding direction, upon radial expansion of members 12. In this embodiment spirals 16 are formed in alternate wound structures so that some unwind in one direction and some in the other direction. Of course, in any embodiment the spirals can be formed so that they all unwind in one direction, either clockwise or counterclockwise and they may have more or fewer members 13. Also, more or less spirals may be included between the segments. The uncapping is accompanied by a straightening action with respect to members 13 as is described in more detail in connection with Figures 4-8. It can be seen from Figures 4 through 8 that the resultant configuration in an expanded stent of this configuration is comprised of a plurality of cells, the perimeter of each of which is defined by a pair of members or struts defined by the loop portion 14 of segment 12 and a pair of members or struts 13. The cells are joined at 16 as best seen in Figure 8. More specifically the cells are of two kinds as shown in Figure 8. A first pair of cells are A and B made up of a segment 12 and two struts 13a for cell A or 13b for cell B. A second pair of cells are C and D made up of an inward-loop portion 14 of segment 12 and a strut 13a and a strut 13b for cells C and D.

[0010] When a stent of the invention, such as that shown in Figures 1-4 undergoes expansion, such as from the embodiment of Figure 4, it will appear as shown in Figure 5 in the fully expanded condition. Figure 5 shows the stent in perspective.

[0011] The unwinding action which the coil elements 16 undergo upon stent expansion is best seen in Figures 6-8 which show only the front side surface of the stent for simplicity and clarity.

[0012] As radial expansion begins (seen in Figure 6) it can be appreciated that the coil elements 16 undergo an unwinding or straightening action by a pulling force on all of the members 13. Specifically, as expansion occurs, elements 13 undergo a straightening action as can be seen in the early stages of expansion in Figure 6.

[0013] Upon further expansion (seen in Figure 7), spirals 16 undergo further unwinding, i.e., elements 13 undergo further straightening.

[0014] Finally in Figure 8, substantial full expansion provides substantially straightened elements 13 which in that condition limit stent recoil and increase the resistance to compression of the stent.

[0015] Figure 9 shows a modified embodiment in which elements 13a and 13b contact segment 12 at the end of its loops 14. Also note in this embodiment that the coils 16 are all wound in the same direction.

[0016] Figure 10 shows an embodiment of the invention in which the spiral members 13 are more bent and less curvilinear but still form a coil-like configuration 16. The remainder of the configuration is similar to that of Figure 9. In Figure 10, elongate members 13 are shown prior to expansion of the stent. When the stent is expanded, members 13 unwind counter-clockwise and straighten somewhat. At full expansion members 13

straighten still further and straighten substantially so as to provide resistance to compression of the stent and low recoil. The expanded configuration displays a cell configuration similar to that seen in Figure 8.

[0017] Other embodiments are shown in subsequent Figures with different coil arrangements. For example, the embodiment of Figures 11-13 shows coiled arrangements 16 which are wound in the same direction and elements 13 attached at the end of loops 14 while some adjacent coils between segments are interconnected by members 15.

[0018] Figure 14 shows some elements 13 in a spiral 16 contacting the end of loops 14 and some contacting segment 12 proper. Also, some adjacent coils are interconnected by members 17.

[0019] Figure 15 shows a flattened or elongated spiral arrangement 16 and elements 12 are angled with respect to the longitudinal axis of the stent. In previous embodiments, these elements or segments have been arranged parallel to the axis or horizontal. Elongated spirals as in Figure 13 and coils of previous Figures may be mixed together. (Not shown).

[0020] In the embodiments already discussed, annular expandable segments such as segments 12 are interspersed with coil arrangements 16. However, as can be seen in Figure 16, at least a substantial portion or all of the stent body can be merely comprised of spiral arrangements 16 connected to each other. Actually, all of the body may consist of spirals. In this embodiment, the elements 13 interconnect between spirals over substantially the entire body of the stent. Optionally, the ends may include segments 12 as shown.

[0021] The embodiment shown in Figure 17 shows segments 12 alternately angled in opposite directions and with legs thereof of different length and elements 13 contacting the segments at different locations, i.e., as at the loop portion 14 and at the segment portion proper.

[0022] Figures 18-28 demonstrate examples of what is meant by the terms coil, spiral and coil-like herein. Of course, additional members may be included in the coils.

[0023] The inventive stent may also be provided with alternate segments 12 in serpentine annular configuration interconnected by double rows of interconnected coil configurations 16.

[0024] Coils 16 may be included on the ends of a stent 10.

[0025] While this invention may be embodied in many different forms, there are described in detail herein specific preferred embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

## Claims

1. An expandable stent in the form of a generally tubular body (10), characterized in that the configuration thereof includes one or more spiral elements (16), each spiral element comprised of a plurality of members (13a,b) winding about a common point, the one or more spiral elements disposed about the body of the stent.
2. The stent of claim 1 wherein the spiral elements (16) are at the ends of the stent.
3. The stent of claim 1 in which at least some of the spiral elements (16) are connected to each other.
4. The stent of claim 2 in which the stent body (10) is comprised of substantially all spiral elements (16) interconnected to each other.
5. The stent of claim 1 in which at least some of the spiral elements (16) are interconnected between other stent elements.
6. The stent of claim 5 wherein the other stent elements are annular serpentine elements (12).
7. The stent of claim 6 wherein the serpentine portions of the elements (12) are longitudinally arranged with respect to the longitudinal axis of the stent.
8. The stent of claim 6 wherein the serpentine portions of the elements (12) are angularly arranged with respect to the longitudinal axis of the stent.
9. The stent of claim 1 comprising a plurality of interconnected expandable cells, included first cells each of which is comprised of a plurality of joined struts (13a,b) to form a perimeter of each cell, two of which are adjacent and curvilinear (13a) and meet two similarly arranged struts (13b) of an adjoining cell to form a said spiral element (16) at the joined ends of each first cell and on expansion of the stent, all struts (13a,b) of each first cell undergo deformation and the spiral elements undergo straightening whereby the two struts (13a,b) of each first cell forming spiral elements undergo a straightening action.
10. The stent of claim 9 wherein the straightening action is an unwinding action.
11. The stent of claim 9 wherein two of the struts, other than the two curvilinear struts, forming a cell are a portion of a serpentine annular element (12), a plurality of which are in spaced arrangement.
12. The stent of claim 1 comprised of:

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a plurality of longitudinally aligned and expandable segments of generally cylindrical configuration (12), expansion enlarging the diameter of the segments, at least one connector element (13a) extending from a segment (12) to join a corresponding element (13b) extending from an adjacent segment (12), wherein the spiral elements are formed from connectors which wind about a common point between the adjacent segment (12), the connector elements straightening upon expansion of the adjoining segments.

13. The stent of claim 12 wherein there are a pair of connector elements (13a) extending from a segment (12) to join a corresponding pair (13b) extending from an adjacent segment (12).
14. The stent of claim 12 wherein the straightening of the connectors is an unwinding action.
15. The stent of claim 12 wherein the aligned expandable stent segments (12) are in the form of annular serpentine segments.
16. The stent of claim 15 wherein the serpentine portion of the segments (12) are longitudinally arranged with respect to the longitudinal axis of the stent.
17. The stent of claim 15 wherein the serpentine portions of the elements (12) are angularly arranged with respect to the longitudinal axis of the stent.
18. The stent of claim 1 further comprising:

a plurality of expandable segments of generally cylindrical configuration (12); connector elements (13a) extending between the segments (12) to join corresponding elements (13b) extending from an adjacent segment, wherein the spiral elements are formed from connectors which wind about a common point and forming at least one spiral configuration between the segments, the spiral straightening upon stent expansion.

19. The stent of claim 18 wherein the connectors form a plurality of spiral elements (16) between the segments.
20. The stent of claim 18 wherein the straightening involves unwinding of the spiral elements (16).

Patentsprüche

1. Ausdehnbarer Stent in Form eines im allgemeinen röhrenförmigen Körpers (10), dadurch gekennzeich-

net, daß die Konfiguration desselben ein oder mehrere Spiralelemente (16) umfaßt, wobei jedes Spiralelement aus einer Vielzahl von sich um einen gemeinsamen Punkt herum windenden Gliedern (13a, b) umfaßt ist, wobei das eine oder die mehreren Spiralelemente um den Körper des Stents herum angeordnet sind.

2. Stent nach Anspruch 1, wobei sich die Spiralelemente (16) an den Enden des Stents befinden. 10

3. Stent nach Anspruch 1, wobei zumindest einige von den Spiralelementen (16) miteinander verbunden sind. 15

4. Stent nach Anspruch 2, wobei der Stentkörper (10) aus im wesentlichen allen miteinander verbundenen Spiralelementen (16) umfaßt ist. 20

5. Stent nach Anspruch 1, wobei zumindest einige von den Spiralelementen (16) zwischen anderen Stentelementen miteinander verbunden sind. 25

6. Stent nach Anspruch 5, wobei die anderen Stentelemente ringförmige, serpentinartige Elemente (12) sind. 30

7. Stent nach Anspruch 6, wobei die serpentinartigen Abschnitte der Elemente (12) längs in bezug auf die Längsachse des Stents angeordnet sind. 35

8. Stent nach Anspruch 6, wobei die serpentinartigen Abschnitte der Elemente (12) winkelig in bezug auf die Längsachse des Stents angeordnet sind. 40

9. Stent nach Anspruch 1, mit einer Vielzahl von miteinander verbundenen ausdehbaren Zellen, umfassend erste Zellen, von denen jede aus einer Vielzahl von verbundenen Verstrebungen (13a, b) umfaßt ist, um einen Umfang jeder Zelle zu bilden, und von denen zwei benachbart und krummflig sind (13a) und auf zwei ähnlich angeordnete Verstrebungen (13b) einer benachbarten Zelle treffen, um an den verbundenen Enden jeder ersten Zelle und bei Ausdehnung des Stents ein solches Spiralelement (16) zu bilden, alle Verstrebungen (13a, b) jeder ersten Zelle eine Verformung erfahren und die Spiralelemente eine Geraderichtung erfahren, wodurch die zwei Verstrebungen (13a, b) jeder ersten Zelle, die Spiralelemente bilden, einen Geraderichtvorgang erfahren. 45

10. Stent nach Anspruch 9, wobei der Geraderichtvorgang ein Auseinanderwickelvorgang ist. 50

11. Stent nach Anspruch 9, wobei zwei von den Verstrebungen, die andere als die zwei eine Zelle bildenden krummflig Verstrebungen sind, ein Ab-

schnitt eines serpentinartigen, ringförmigen Elementes (12) sind, von denen eine Vielzahl beabstandet angeordnet ist. 55

5 12. Stent nach Anspruch 1, mit: einer Vielzahl von längs geraderichteten und ausdehbaren Segmenten mit im allgemeinen zylindrischer Konfiguration (12), wobei sich der Durchmesser der Segmente durch Ausdehnung vergrößert, mindestens einem von einem Segment (12) ausgehenden Verbinderelement (13a) zum Anschluß an ein von einem benachbarten Segment (12) ausgehendes entsprechendes Element (13b), wobei die Spiralelemente aus Verbindern ausgebildet sind, die sich um einen gemeinsamen Punkt zwischen dem benachbarten Segment (12) winden, wobei sich die Verbinderelemente bei Ausdehnung der benachbarten Segmente geraderichten. 60

13. Stent nach Anspruch 12, wobei zwei Verbinderelemente (13a) vorhanden sind, die von einem Segment (12) ausgehen, um sich an zwei entsprechende, von einem benachbarten Segment (12) ausgehende Verbinderelemente (13b) anzuschließen. 65

14. Stent nach Anspruch 12, wobei der Geraderichtvorgang der Verbinden ein Auseinanderwickelvorgang ist. 70

15. Stent nach Anspruch 12, wobei die ausgerichteten, ausdehbaren Stentsegmente (12) die Form von ringförmigen, serpentinartigen Segmenten aufweisen. 75

16. Stent nach Anspruch 15, wobei die serpentinartigen Abschnitte der Segmente (12) längs in bezug auf die Längsachse des Stents angeordnet sind. 80

17. Stent nach Anspruch 15, wobei die serpentinartigen Abschnitte der Elemente (12) winkelig in bezug auf die Längsachse des Stents angeordnet sind. 85

18. Stent nach Anspruch 1, des weiteren mit: einer Vielzahl von ausdehbaren Segmenten mit im allgemeinen zylindrischer Konfiguration (12), wobei sich zwischen den Segmenten (12) Verbinderelemente (13a) erstrecken (13a), zum Anschluß an von einem benachbarten Segment (12) ausgehende entsprechende Elemente (13b), wobei die Spiralelemente aus Verbindern ausgebildet sind, die sich um einen gemeinsamen Punkt herum winden und mindestens eine Spiralkonfiguration zwischen den

Segmenten bilden, wobei sich die Spirale bei Ausdehnung des Stents geraderichtet.

18. Stent nach Anspruch 18, wobei die Verbindungen eine Vielzahl von Spirelementen (16) zwischen den Segmenten bilden.

19. Stent nach Anspruch 18, wobei beim Geraderichten die Spirelemente (16) auseinander gewickelt werden.

**Revendications**

1. Stent expansible sous la forme d'un corps (10) généralement tubulaire, caractérisé en ce que la configuration de celui-ci comprend un ou plusieurs éléments en spirale (16), chaque élément en spirale étant constitué d'une pluralité d'éléments (13a,b) s'enroulant autour d'un point commun, un ou plusieurs des éléments en spirale étant disposés sur le corps du stent.
2. Stent de la revendication 1 dans lequel les éléments en spirale (16) sont situés aux extrémités du stent.
3. Stent de la revendication 1 dans lequel au moins certains des éléments en spirale (16) sont reliés les uns aux autres.
4. Stent de la revendication 2 dans lequel le corps (10) du stent est constitué d'éléments sensiblement tous en spirale (16) interconnectées les uns aux autres.
5. Stent de la revendication 1 dans lequel au moins certains des éléments en spirale (16) sont interconnectés entre d'autres éléments en spirale du stent.
6. Stent de la revendication 5 dans lequel les autres éléments du stent sont des éléments en serpentins annulaires (12).
7. Stent de la revendication 6 dans lequel les parties en serpentins des éléments (12) sont disposées longitudinalement par rapport à l'axe longitudinal du stent.
8. Stent de la revendication 6 dans lequel les parties en serpentins des éléments (12) sont disposées de façon angulaire par rapport à l'axe longitudinal du stent.
9. Stent de la revendication 1 comprenant une pluralité de cellules expansibles interconnectées, y compris des premières cellules dont chacune est composée d'une pluralité d'entretoises jointives (13a,b) pour former le périmètre de chaque cellule, deux d'entre elles étant adjacentes et curvilignes (13a) et rejoignant deux entretoises (13b), disposées de façon similaire, d'une cellule contiguë pour former un dit élément en spirale (16) aux extrémités jointives de chaque première cellule et lors de l'expansion du stent, toutes les entretoises (13a,b) de chaque première cellule subissent une déformation et les éléments en spirale subissent un redressement, grâce à quoi les deux entretoises (13a,b) de chaque première cellule formant des éléments en spirale subissent une action de redressement.
10. Stent de la revendication 9 dans lequel l'action de redressement est une action de déroulement.
11. Stent de la revendication 9 dans lequel deux des entretoises, autres que les deux entretoises curvilignes, formant une cellule sont une partie d'un élément en serpentin annulaire (12), une pluralité d'entretoises est disposée selon une relation espacée.
12. Stent de la revendication 1 comprenant :
13. une pluralité de segments expansibles et alignés longitudinalement de configuration généralement cylindrique (12), l'expansion élargissant le diamètre des segments, au moins un élément connecteur (13a) s'étendant depuis un segment (12) pour rejoindre un élément correspondant (13b) s'étendant depuis un segment adjacent (12), dans lequel les éléments en spirale sont formés de connecteurs qui s'enroulent autour d'un point commun entre le segment adjacent (12), les éléments connecteurs se redressant lors de l'expansion des segments contigus.
14. Stent de la revendication 12 dans lequel il existe une paire d'éléments connecteurs (13a) s'étendant depuis un segment (12) pour rejoindre une paire correspondante (13b) s'étendant depuis un segment adjacent (12).
15. Stent de la revendication 12 dans lequel le redressement des connecteurs est une action de déroulement.
16. Stent de la revendication 12 dans lequel les segments de stent expansibles alignés (12) sont sous la forme de segments en serpentins annulaires.
17. Stent de la revendication 15 dans lequel les parties en serpentins des éléments (12) sont disposées longitudinalement par rapport à l'axe longitudinal du stent.
18. Stent de la revendication 15 dans lequel les parties en serpentins des éléments (12) sont disposées de façon angulaire par rapport à l'axe longitudinal du

stent.

**18. Stent de la revendication 1 comprenant en outre :**

une pluralité de segments expansibles de configuration généralement cylindrique (12) ;  
des éléments connecteurs (13a) s'étendant entre les segments (12) pour rejoindre les éléments correspondants (13b) s'étendant depuis un segment adjacent, dans lequel les éléments en spirale sont formés de connecteurs qui s'enroulent autour d'un point commun et formant au moins une configuration en spirale entre les segments, la spirale se redressant lors de l'expansion du stent. 5

**19. Stent de la revendication 18 dans lequel les connecteurs forment une pluralité d'éléments en spirale (16) entre les segments.**

**20. Stent de la revendication 18 dans lequel le redressement implique le déroulement des éléments en spirale (16).**

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See Fig. 2

Fig. 1

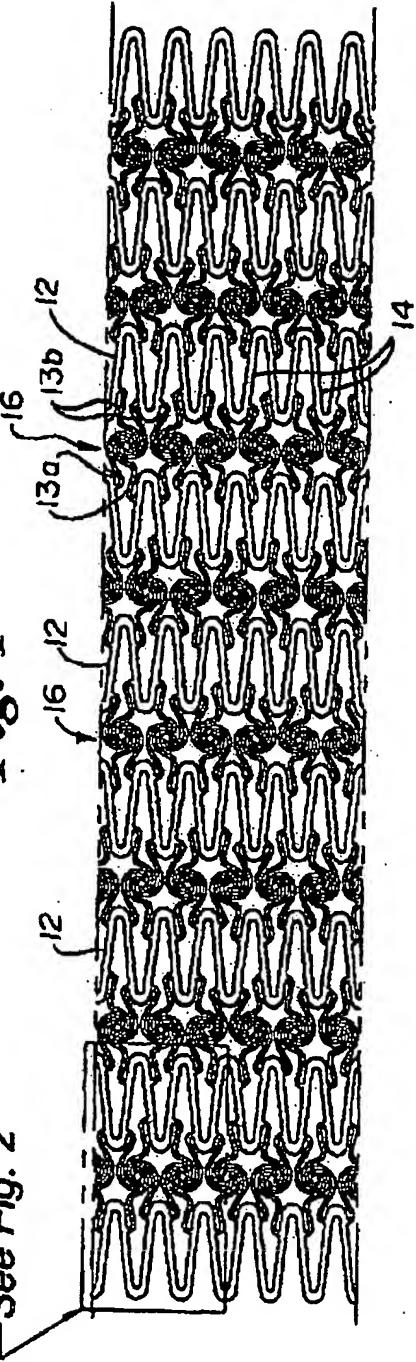


Fig. 2

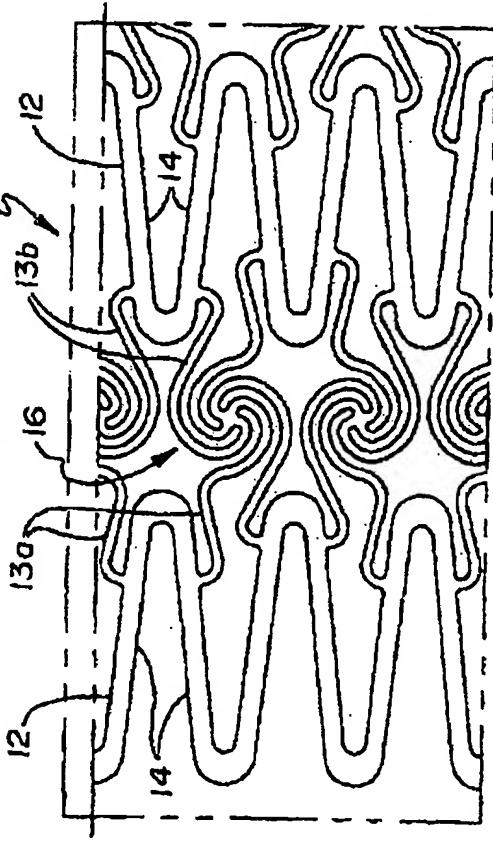


Fig. 3

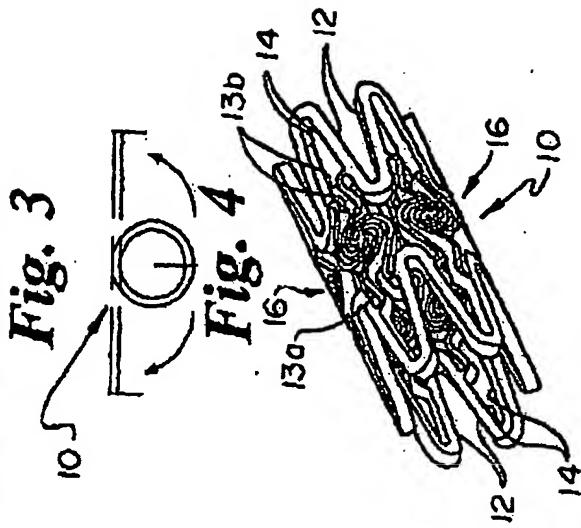
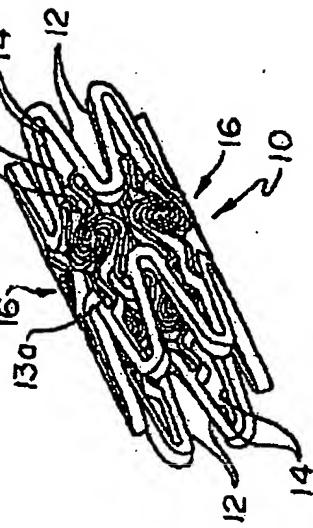
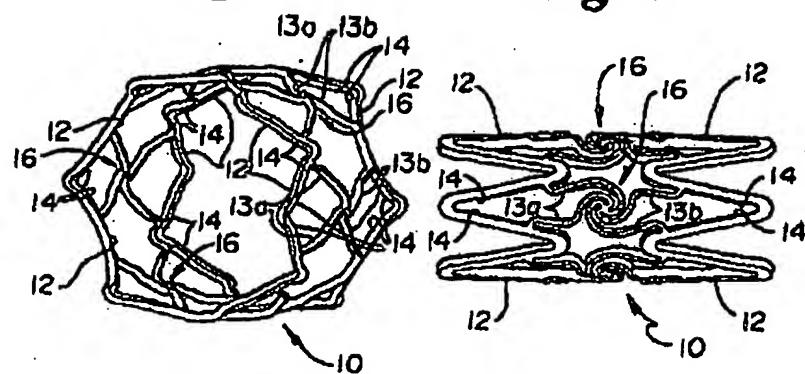


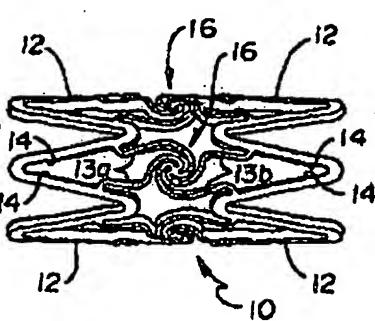
Fig. 4



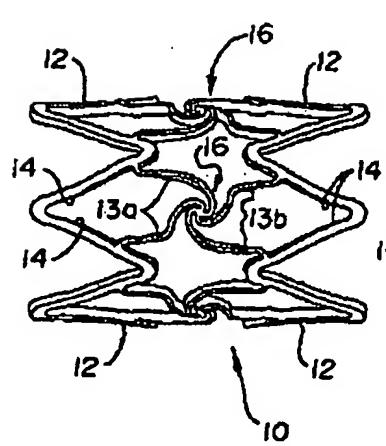
*Fig. 5*



*Fig. 6*



*Fig. 7*



*Fig. 8*

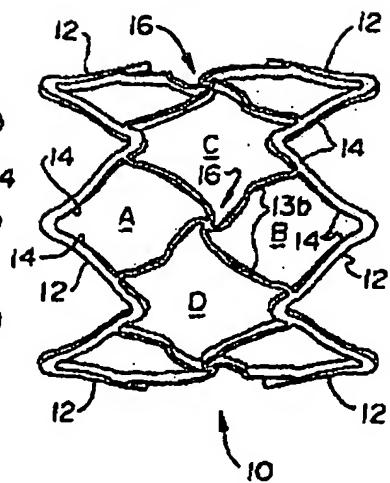


Fig. 9

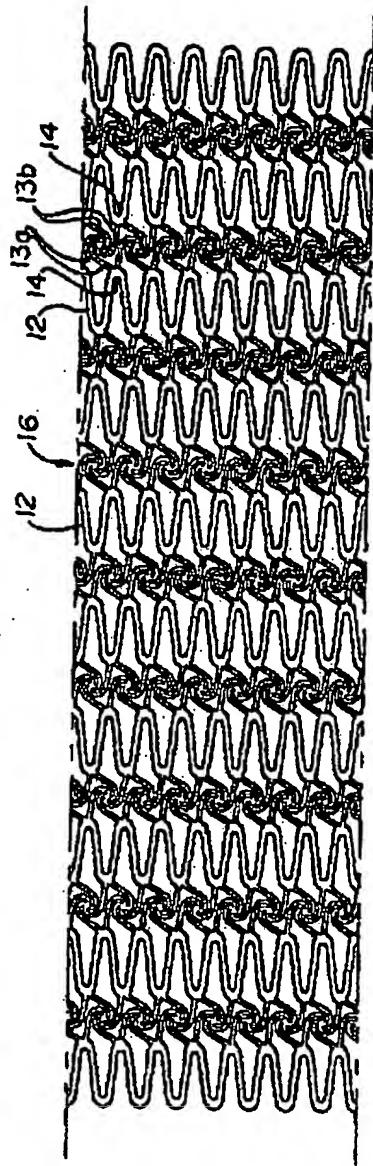
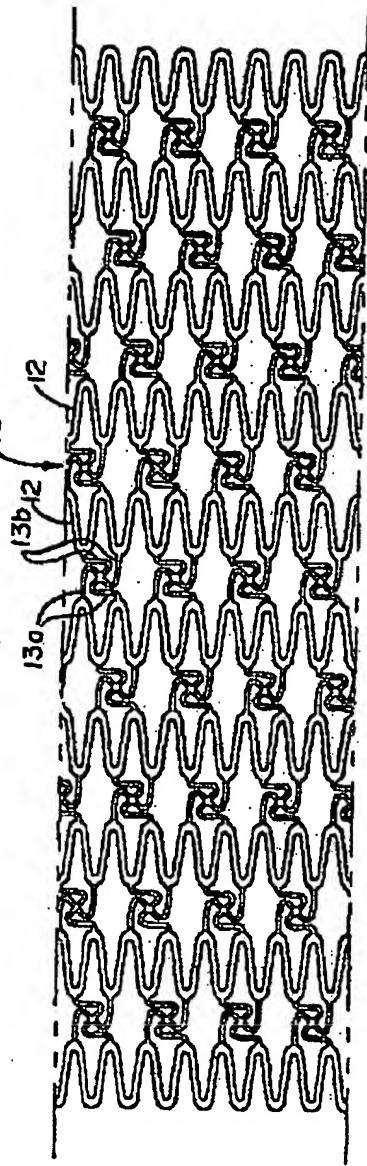
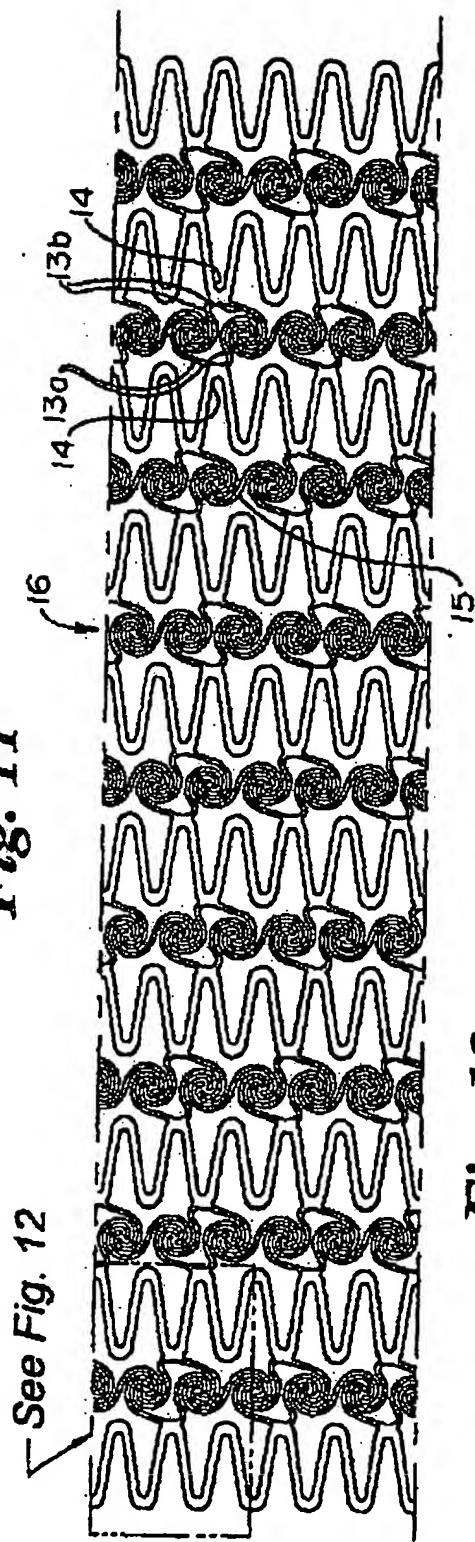


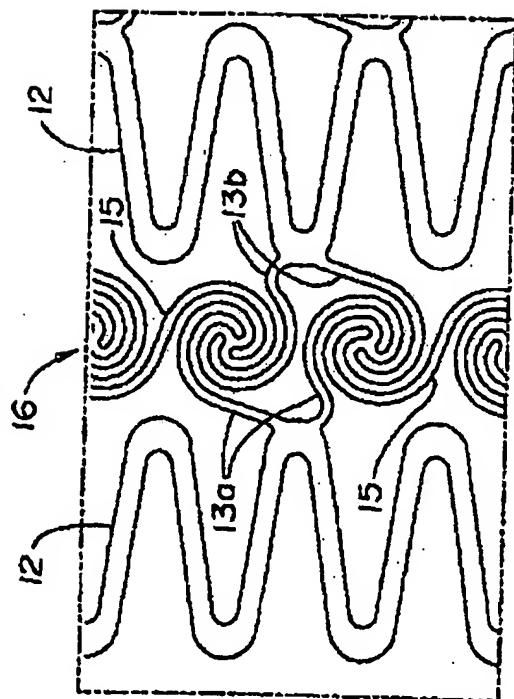
Fig. 10



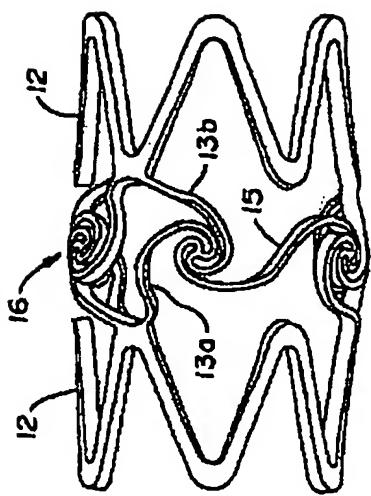
*Fig. 11*



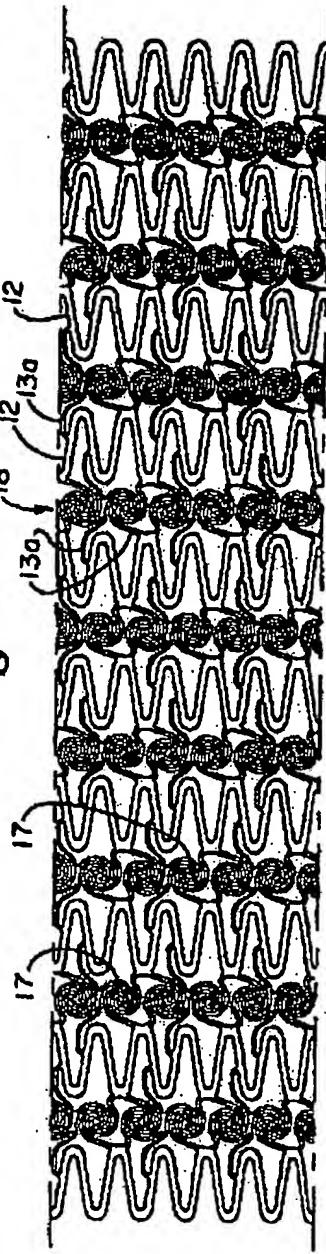
*Fig. 12*



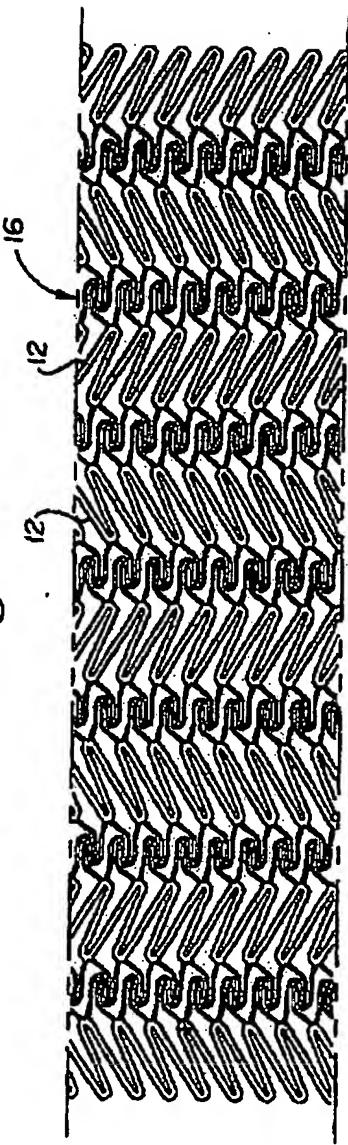
*Fig. 13*



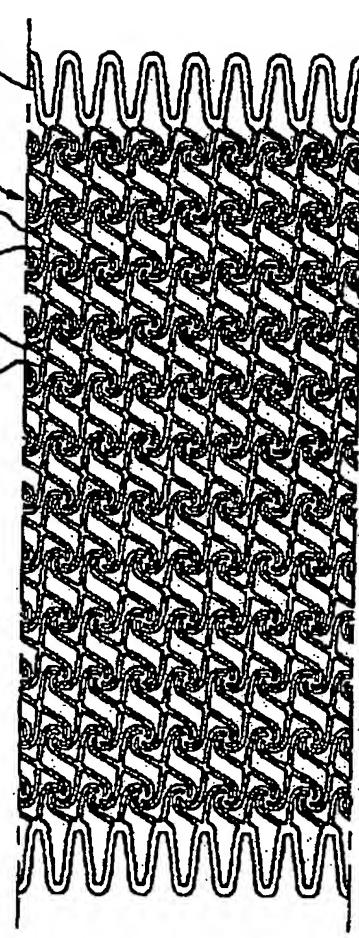
*Fig. 14*



*Fig. 15*



*Fig. 16*



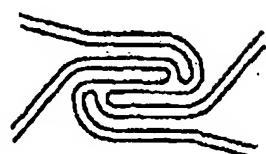
*Fig. 17*

16  
12  
12  
14

*Fig. 18*



*Fig. 19*



*Fig. 20*



*Fig. 21*



*Fig. 22*



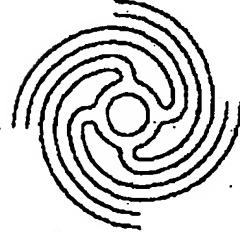
*Fig. 23*



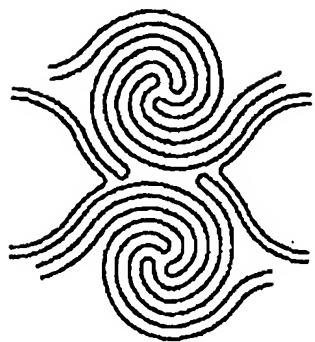
*Fig. 24*



*Fig. 25*



*Fig. 26*



*Fig. 27*



*Fig. 28*



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